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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,572	04/19/2004	Lowell L. Wood JR.	SE1-0034-US	3210

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EXAMINER	
CAMPBELL, VICTORIA P	
ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,572	WOOD, LOWELL L.	
	Examiner	Art Unit	
	VICTORIA P. CAMPBELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *35-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34 and 66-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2009* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/09 9/1/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the third Office Action based on the 10/827572 application filed April 19, 2004. Claims 1-34 and 66-68 as amended are currently pending and considered below.

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings currently submitted by applicant are elementary in nature and not sufficient to describe the invention (most notably figures 3, 4, and 5). The examiner further notes that Figure 3 appears to be comprised of 3 separate figures, none of which is currently labeled independently (i.e.: 3A, 3B, and 3C).

2. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Terminal Disclaimer

5. The terminal disclaimer filed on July 23, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/827576 and 10/827390 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPGPub 2002/0065509 A1 to Lebel et al in view of USPGPub 2005/0004553 A1 to Douk.

Regarding the above claims, Lebel et al teach a device comprising a body portion (6); at least one extensible finger (16) coupled to said body portion; at least one reservoir (84) in communication with said extensible finger; and a control circuitry (Paragraph [0140]) coupled to said body portion. Lebel et al further disclose a device for data storage [0139], a sensor [0152], a pump or actuator (86; [0140]), a wireless data transmitter and receiver or controller ([0141]-[0148]), and a source of a drug [0139]. Lebel et al further disclose a device for shunting flow (16), and a fluid dispenser carried by the extensible finger (terminal end of catheter 16) to operate at a controlled rate [0160]. Lebel et al also disclose a processor (72), software [0148], that the device is configured for full placement in vivo, in a human animal, in a location corresponding to one physiological variable that needs to be treated (Abstract). Furthermore, Lebel et al disclose that the device provides a treatment to the patient comprising a medical agent (insulin delivery), and that the device communicates exterior to the patient (Fig. 3). Lebel et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406; Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches

that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Lebel et al, because doing so would allow the physician to change the length of the catheter *in vivo* instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.

Regarding claims 9 and 31, Lebel et al and Douk teach the device of claims 1 and 30 as described above, but fail to teach that the delivered compound is a combination of two or more substances, or that the device is implanted in the vasculature. However, combination of drugs or substances for delivery is known in the drug delivery art, as is placement of the delivery device in the blood stream. Therefore, both of these limitations would have been obvious to one having ordinary skill in the art at the time the invention was made.

9. Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 4,944,659 to Labbe et al in view of USPGPub 2005/0004553 A1 to Douk.

Regarding the above claims, Labbe et al disclose a device comprising a body portion (3); at least one extensible finger (20) coupled to said body portion; at least one reservoir (12) in communication with said extensible finger; and a control circuitry (Figure 4) coupled to said body portion. Labbe et al further disclose a device for data storage (Fig. 4), a sensor (70; Col. 4, lines 11-16), a pump or actuator (52), a wireless data transmitter and receiver or controller (60), and a source of a drug (Col. 4, lines 24-25). Labbe et al further disclose a device for shunting flow (20), and a fluid dispenser carried by the extensible finger (terminal end of catheter 20) to operate at a controlled rate (Col. 4, lines 18-30). Labbe et al also disclose a processor (66), software (Fig. 4; Col. 4, lines 3-18), that the device is configured for full placement in vivo, in a human animal, in a location corresponding to one physiological variable that needs to be treated (Col. 2, lines 55-60). Furthermore, Labbe et al disclose that the device provides a treatment to the patient comprising a medical agent (Col. 2, lines 56-58), and that the device communicates exterior to the patient (Col. 2, lines 59-60). Labbe et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via

positioning wire 406; Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Labbe et al, because doing so would allow the physician to change the length of the catheter *in vivo* instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.

Regarding claims 9 and 31, Labbe et al and Douk teach the device of claims 1 and 30 as described above, but fail to teach that the delivered compound is a combination of two or more substances, or that the device is implanted in the vasculature. However, combination of drugs or substances for delivery is known in the drug delivery art, as is placement of the delivery device in the blood stream. Therefore, both of these limitations would have been obvious to one having ordinary skill in the art at the time the invention was made.

10. Claims 1, 10-16, 18, 19, 23, 24, and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,296,638 B1 to Davison et al in view of USPGPub 2005/0004553 A1 to Douk.

Regarding the above claims, Davison et al disclose a device comprising a body portion (10); at least one extensible finger (42) coupled to said body portion; at least one reservoir (32) in communication with said extensible finger; and a control circuitry (Col. 17, lines 40-49) coupled to said body portion. Davison et al further disclose an operative tool in communication with the extensible finger (102, 103, 104), as well as a tool positioner (handle 204). Davison et al also disclose that the operative tool is a device for ablation (Col. 19, lines 7-9), that the control circuitry guides (provides complete control over) the tool (Col. 17, lines 40-42), and a source of electric charge (10). Davison et al also disclose a device for evacuating a target or cauterizing (102, 103, 104), and that the control circuitry is coupled to guide or control the extensible finger (10). Davison et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406; Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably

collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Davison et al, because doing so would allow the physician to change the length of the catheter during a procedure instead of being attached to a particular length chosen prior to the start of a surgical procedure.

11. Claims 1 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,086,528 to Adair in view of USPGPub 2005/0004553 A1 to Douk.

Regarding the above claims, Adair teaches a body (handle), an extending part (probe), at least one receiving body (syringe) and a control circuit. The system also teaches use in stent delivery (Col. 2, lines 25-30). Adair does not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406; Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent

segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Adair, because doing so would allow the physician to change the length of the catheter during a procedure instead of being attached to a particular length chosen prior to the start of a surgical procedure.

Response to Arguments

12. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
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